ANITA MENON

The Launch Sequence

Who does what, and when. Two sequences, because specialty and primary care are not the same launch and pretending otherwise costs you a year.

WHO THIS IS FOR

Affiliate general managers and commercial leads, and the cross-functional team around them: regulatory, market access, medical, supply, commercial, sales and finance. Most useful if you have just been told a product is coming, if you are building a year one number, or if you are running the same launch plan in specialty and primary care.

ANITA MENON

Commercial leadership across the GCC, India and APAC

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Count back from the first order, not from approval

Almost every launch plan I have seen in this region is built around the approval date. Money does not start then. It starts when a hospital or a ministry places the first order, and that is usually **nine to eighteen months later**. Nobody owns that gap, so nobody closes it.

Registration got fast. Saudi Arabia aims to clear a file in thirty working days, Indonesia in ninety. Everything after it did not. The committee that decides what gets paid for still meets when it meets. The tender still opens when it opens. And the local manufacturing rules quietly decide whether you can compete on price at all.

So the two grids that follow count back from the **first order**. Columns are windows of time. Rows are functions. Each box is what that team needs to have finished.

They are separate because the route to first money is genuinely different. In specialty you can win one hospital and start earning before there is a national listing. In primary care there is no shortcut. You wait for the list, then you win or lose on price.

HOW TO USE IT

Put a name against every box. Not a function, a person. Every empty box is somewhere the launch will slip, and you will only find out later.

The shaded column is the one that gets missed. It is where money actually starts, and it is usually where the team is still getting ready.

If you have less than eighteen months notice, which is normal, go to page six first.

TRY THIS IN YOUR NEXT REVIEW

Ask for the date a hospital can place its first order, and the name of the person who owns that date. If you do not get both, you are not ready. I do not care what the scorecard says.

Specialty care

	24 TO 18 MONTHS OUT	18 TO 12 MONTHS OUT	12 TO 6 MONTHS OUT	6 MONTHS TO FIRST ORDER	FIRST 12 MONTHS
Regulatory	Confirm which fast route applies and when the FDA or EMA decision is expected. Appoint the local agent.	File the day the reference decision lands. The dossier is already complete.	Clear queries. Secure the pricing certificate.	Registration and price in place.	Variations, renewals, label extensions.
Market access	List the countries that copy your price. Assemble local patient numbers and cost data.	Build the budget impact and cost file on local inputs. Name the committee meeting and its paperwork deadline.	Submit to the committee. Open talks on a managed entry deal if the price is high.	Committee decision. Get onto the institution's own formulary.	Track funded patients, not everyone eligible.
Medical	Identify the two or three centres that set practice. Map the treating clinicians, not the speaker list.	Open early access or named patient where allowed. Start collecting outcomes from the first patients.	Present local experience. Feed it into the committee submission.	Support the first protocol change inside the reference centre.	Turn first patient outcomes into evidence for the next market.
Supply and partners	Decide the local manufacturing answer. Shortlist contract partners if a price preference applies.	Sign the contract manufacturing or fill and finish agreement.	Stock in country before the committee decides, not after.	Serve the first institution.	Scale to the next centres.
Commercial	Decide which single institution you will win first.	Build the case for that institution, not a national campaign.	Get the private and insured channel ready to sell.	First private sales. First tender or direct purchase.	Second and third institution.
Sales	*Do not hire yet.*	*Do not hire yet.*	Define a small, senior account team.	Hire against funded patients.	Add heads only as institutions open.
Finance	Model revenue from the first order, not from approval.	Take the published tender and committee dates to the global forecast discussion.	Lock the year one number against the committee date.	Hold the number.	Report against funded patients.

THE SHORTCUT WORTH TAKING

One hospital can buy before any national listing exists. Win it properly and it pays twice. It earns, and it becomes the argument you put in front of the committee later.

Primary care

	24 TO 18 MONTHS OUT	18 TO 12 MONTHS OUT	12 TO 6 MONTHS OUT	6 MONTHS TO FIRST ORDER	FIRST 12 MONTHS
Regulatory	Confirm the fast route and the expected FDA or EMA decision date. Appoint the agent.	File the day the reference decision lands.	Clear queries. Secure the pricing certificate.	Registration and price in place.	Watch generic entry and the price erosion rules that follow.
Market access	Understand the local manufacturing price preference. Here it often decides the tender.	Build the cost file knowing you will be judged on price per patient, not on novelty.	Submit for national listing. There is no institution shortcut.	Tender. Price is the decision.	Defend the price at the first review.
Medical	Work on guideline position, not on individual centres.	*Limited role at this stage.*	Guideline inclusion and primary care education.	Support the listing submission.	Real world use data for the price defence.
Supply and distribution	Decide the local manufacturing answer. The preference bites hardest here because you compete on price.	Sign the contract. Confirm distributor coverage across the whole country.	Agree retail and pharmacy chain terms. Plan stock across every point of sale.	Retail and dispensing channels live on day one of listing.	Fill rate is the metric that matters.
Commercial	Decide honestly whether you can win on price. If not, say so now.	Build the listing case, not the campaign.	Retail and pharmacy readiness. Patient support if co-payment is high.	Listing, then distribution, then promotion. In that order.	Share of voice only once you are on the list and in stock.
Sales	*Do not hire yet.*	*Do not hire yet.*	Size the team against the listed indication, not the whole market.	Hire only after listing is confirmed.	Reach and frequency against dispensing data.
Finance	Model revenue from listing plus distribution, not from approval.	Take the tender calendar to the global forecast discussion.	Model the price preference against a local competitor.	Lock year one against the tender award date.	Model generic entry from day one.

NO SHORTCUT HERE

Nothing much happens before the national listing. Once you are on it, the decision is price and whether you are in stock. Run a campaign before listing and you are paying to teach people to ask for something they cannot get.

What changes between the two

Same functions, same calendar, different route to the money. These are the eight places I see teams get caught running one playbook across both.

	SPECIALTY CARE	PRIMARY CARE
Where first revenue comes from	One institution, before national listing	Only after national listing
What actually wins	Clinical conviction at two or three centres	Price, and being in stock
Local manufacturing rules	A disadvantage you can usually price	Often decides the tender
Sales team	Small, senior, hired after the committee	Large, hired only after listing
The shortcut	Named patient, early access, one hospital formulary	There is not one
Medical affairs	Central, from the start	Guidelines, and later
Biggest risk	Getting stuck inside one centre	Losing the tender on price
What to watch after	Whether the second institution opens	Generic entry and the price review

BOTH MISTAKES ARE EXPENSIVE

Run the primary care plan in specialty and you waste the eighteen months when one hospital could already have been buying. Run the specialty plan in primary care and you build demand for something no pharmacy can dispense.

If you only have twelve months

This is the normal case, not the exception. Twelve to eighteen months notice, and the price and the filing order were settled somewhere else before anyone told you. So the question is **what to drop, what to speed up, and what you must not let slip.**

DROP	SPEED UP	PROTECT
Running a new local study from scratch.	Local evidence: assemble it from hospital records, registries, claims and nearby countries. Weeks, not years.	The fast route window. It opens when the FDA or EMA approves and the shortest one shuts three months later.
Building a local factory.	Local manufacturing: contract with a plant that is already licensed. Months, not years.	The committee paperwork deadline. Miss it and the next meeting is a cycle away.
Trying to change the global price. It was set before you were told.	The cost file: put local numbers into the global model instead of building a new one.	The tender window. Saudi Arabia runs four medicine tenders a year.

WHAT STILL WORKS AT TWELVE MONTHS

In specialty, most of it. One hospital, early access, private and insured sales. In primary care, much less, because nothing moves before the listing. If you have twelve months in primary care, the conversation with global is about the year one number. It is not about working harder.

Eight moves that buy time

None of these need a longer runway, more money, or permission from anyone.

1 **File the day the FDA or EMA decision lands, not weeks after.**

Have the local file finished and the agent appointed before the decision lands. It costs nothing and buys three to twelve months. It gets missed because the global filing plan never asks for it, and nobody volunteers work nobody asked for.

2 **Tell the committee you are coming before registration finishes.**

Several systems take an intent or a pre-submission while regulatory is still running. Doing this early can save a whole cycle, which is four months to a year.

3 **Assemble local evidence. Do not commission it.**

Hospital records, registries, insurance claims, published regional studies and a short clinician survey will satisfy most payers here. Budget a local health economist and eight weeks.

4 **Buy the local manufacturing answer rather than building it.**

A contract or fill and finish deal with an already licensed plant can be signed in months. Against a price penalty that can reach thirty per cent, the numbers usually work on the contract alone.

5 **Find the channel that does not wait for the tender.**

Private and insured hospitals, direct purchase outside the main tender, named patient and early access. It will not carry the whole number. It does bring in money and real clinical use while you wait.

6 **Win one hospital properly, especially in specialty.**

Large centres with their own formulary committees and budgets can buy before the national listing. One hospital actually using the product is worth more to the next committee than any promotion.

7 **Reset the forecast with the calendar, not with your opinion.**

Take the published tender plan and committee dates into the global forecast discussion. A date on an official document wins an argument that your view will not. Do it before the number is locked.

8 **Put one name against the first order date.**

Not the launch date. One person accountable for the day a hospital can first order. In most affiliates nobody owns that date. That is exactly why it slips and nobody notices until the quarter closes.

What this is built on

The calendar facts come from named, dated sources: the Saudi FDA regulatory framework and pricing rules, the NUPCO tender plan, the Saudi local content authority, Singapore's Health Sciences Authority and Agency for Care Effectiveness, Malaysia's drug registration guidance, Thailand's essential medicines list announcements, Indonesia's BPOM and health ministry regulations, Vietnam's pharmacy law and its circulars, Philippine FDA circulars and the 2024 procurement act, and the World Health Organization maturity registers.

WHAT IS JUDGEMENT, NOT DATA

The windows in the two grids are working intervals, not measured averages. No regulator here publishes how long it actually takes, and no published figure exists for the lag from registration to first order in any of these markets. Treat the shape as the argument and adjust the months to your own experience.

WORTH CHECKING LOCALLY

Three things in this document are operational practice rather than published rule: that a committee will take an intent before registration completes, that direct purchase routes exist outside the main tender, and that large hospitals can buy ahead of national listing. All three hold in my experience. Confirm each with your own affiliate before you build a plan on it.

Run it against your own launch, and tell me what you found.

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